

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG -6 2012

Mr. Thomas W. Isaac
Senior Regulatory Specialist
Stepan Company
22 W. Frontage Rd.
Northfield, Illinois 60093

Subject: **BTC® 2125M -P40 Sanitizer Concentrated Powder**
EPA Registration Number 1839-142
Application Dated May 25, 2012
EPA Received May 29, 2012

Dear Mr. Isaac:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Amendment:

- Addition of an alternate small packet label with modified text to accommodate a 1" X1" packet size

General Comments:

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,


Velma Noble

Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: stamped label

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

2/8

BTC[®] 2125M-P40 SANITIZER CONCENTRATED POWDER

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 6 2012

ACTIVE INGREDIENTS

Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈)

dimethyl benzyl ammonium chlorides 20.0%

Alkyl (68% C₁₂, 32% C₁₄) dimethyl

ethylbenzyl ammonium chlorides 20.0%

INERT INGREDIENTS 60.0%

Total 100.0%

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

1839-142

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.

If swallowed: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

(OPTIONAL) You may contact xxx/xxx-xxxx for emergency medical treatment information.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

See side (back) panel for additional precautionary statements.

EPA REG. NO. 1839-142

EPA EST. NO. 1839-IL-01

STEPAN COMPANY

22 West Frontage Road
Northfield, IL 60093

NET CONTENTS:

0.0625 ounce per packet per tablet or
0.125 ounce per packet per tablet or
0.1875 ounce per packet per tablet or
0.3125 ounce per packet per tablet or
0.625 ounce per packet per tablet or
1.25 ounce per packet per tablet

AUG 6 2012

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
labeled under EPA Reg. No. 1839-142

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. 1839-142

BTC® 2125M-P40 Sanitizer Concentrated Powder (product name) is designed specifically for use in restaurants, dairies, and bars where sanitization of food contact surfaces is of prime importance.

This product (product name) will sanitize previously cleaned and rinsed non-porous food contact surfaces such as tanks, counter tops, drinking glasses and eating utensils. When used at the recommended concentration of 200-400 ppm, no potable water rinse is required.

When used as directed, this product (product name) is an effective sanitizer against Escherichia coli ATCC 11229, Staphylococcus aureus ATCC 6538, Campylobacter jejuni ATCC 29428, Escherichia coli O157:H7 ATCC 43895, Listeria monocytogenes ATCC 35152, Yersinia enterocolitica ATCC 23715 when diluted in water up to 650 ppm hardness (CaCO₃).

SANITIZATION - Remove all gross food particles and soil from areas which are to be sanitized with a good detergent, pre-flush, pre-soak or pre-scrape treatment. Rinse with a potable water rinse. To sanitize pre-cleaned and potable water-rinsed, non-porous, food contact surfaces, prepare a 200-400 ppm active quaternary solution by using the following dilution table:

In order to make X gallons of Solution	Add Net Weight of Product			
	in Ounces	or in Grams		
1	0.0625 - 0.125	1.8 - 3.6	or ONE - TWO 0.0625 oz. Pack- et(s)	or ONE - TWO 0.0625 oz. Tablet(s)
2	0.125 - 0.25	3.5 - 7.0	or ONE - TWO 0.125 oz. Packet(s)	or ONE - TWO 0.125 oz. Tablet(s)
3	0.1875 - 0.375	5.3 - 10.6	or ONE - TWO 0.1875 oz. Packet(s)	or ONE - TWO 0.1875 oz. Tablet(s)
5	0.3125 - 0.625	8.9 - 17.8	or ONE - TWO 0.3125 oz. Packet(s)	or ONE - TWO 0.3125 oz. Tablet(s)
10	0.625 - 1.25	17.7 - 35.4	or ONE - TWO 0.625 oz. Packet(s)	or ONE - TWO 0.625 oz. Tablet(s)
20	1.25 - 2.5	35.4 - 70.8	or ONE - TWO 1.25 oz. Packet(s)	or ONE - TWO 1.25 oz. Tablet(s)

To sanitize immobile items such as tanks and counter tops, apply sufficient use-solution by low pressure coarse sprayer, hand pump trigger sprayer, mop, sponge or cloth to flood the area with a 200-400 ppm active quaternary solution for at least 60 seconds making sure to wet all surfaces completely. Drain the use-solution from the surface and air dry. Prepare a fresh use-solution daily or more frequently as soil is apparent.

To sanitize mobile items such as drinking glasses and eating utensils, immerse in a 200-400 ppm active quaternary solution for at least 60 seconds making sure to immerse completely. Remove, drain the use-solution from the surface and air dry. Prepare a fresh use-solution daily or more frequently as soil is apparent.

When used for sanitization of previously cleaned food equipment or food contact items, limit the active quaternary to 200-400 ppm. NO POTABLE WATER RINSE IS ALLOWED. This product (product name) is an effective sanitizer when diluted in water up to 650 ppm hardness (CaCO₃).

To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants, spray with a solution of warm water at 200-400 ppm quat (see Dilution Table above). The use-solution should be warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this use-solution shall be subjected to a potable water rinse only if they are broken immediately for use in the manufacture of egg products. Eggs should be reasonably dry before casing or breaking. The use-solution should not be reused for sanitizing eggs.

PACKETS: (If using packets, use either the tear open or water soluble instructions)

(Tear open packet) Follow label dilution instructions and discard opened packet according to label disposal instructions.

(Water soluble packet) Follow label instructions by dropping packet directly into water. Do not remove packets before use.

TABLETS: Follow label dilution instructions by dropping tablet directly into water. Do not remove tablets from container before use.

DIRECTIONS FOR SANITIZING FOOD PROCESSING EQUIPMENT, UTENSILS, AND FOOD CONTACT ARTICLES REGULATED BY 40CFR180.940.

1. Scrape, flush or pre-soak articles (whether mobile or stationary) to remove gross food particles and soil.
2. Thoroughly wash articles with an appropriate detergent or cleaner.
3. Rinse articles thoroughly with potable water.
4. Sanitize articles using a solution of 0.3125–0.625 ounce of this product (product name) per 5 gallons of water (or equivalent dilution) (200-400 ppm active quaternary). Articles that can be immersed in use-solution should remain in solution for 60 seconds. Articles too large for immersion should be thoroughly wetted by rinsing, spraying or swabbing.
5. Remove immersed items from use-solution to drain and then air dry. Non-immersed items should also be allowed to air dry.

U.S. PUBLIC HEALTH SERVICE - FOOD SERVICE SANITIZATION RECOMMENDATIONS

CLEANING AND SANITIZING: Equipment and utensils shall be thoroughly pre-flushed or pre-scraped, and when necessary, pre-soaked to remove gross food particles and soil.

1. Thoroughly wash equipment and utensils in a hot detergent solution. Rinse utensils and equipment thoroughly with potable water.
2. Sanitize equipment and utensils by immersing in 0.3125–0.625 ounce of this product (product name) per 5 gallons (or equivalent dilution) of water (200-400 ppm active quaternary) for at least 60 seconds at a temperature of 75°F. This dilution is equivalent to a solution containing 50 ppm available chlorine.
3. Allow sanitized surfaces to drain and air dry. Do not rinse.
4. For equipment and utensils too large to sanitize by immersion, apply 0.3125–0.625 ounce of this product (product name) per 5 gallons of water (or equivalent dilution) (200-400 ppm active quaternary) by rinsing, spraying or swabbing. Allow the items to remain thoroughly wet for at least 60 seconds, then let air dry. Do not rinse.

(This statement is required for marketing food contact sanitizers in Wisconsin.)

WISCONSIN STATE DIVISION OF HEALTH - DIRECTIONS FOR EATING ESTABLISHMENTS:

1. Scrape and pre-wash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner.
3. Rinse with potable water.
4. Sanitize in a solution of 0.3125 ounce of this product (product name) per 5 gallons of water (or equivalent dilution) (200 ppm active quaternary). Immerse all utensils for at least two minutes or for contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drain board to air dry.
6. Fresh sanitizing solution should be prepared at least daily or when visibly soiled or diluted.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196.13 of the Wisconsin Administrative Code.

ACCEPTED

when visibly soiled or diluted.

mitted Under Section

HFS 196.13 of

the Wisconsin Administrative Code.

Under the Federal Insecticide,

Fungicide, and Rodenticide Act as

amended by the pesticide,

Amend 05/25/12

AUG 6 2012

No. 1839-142

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

DANGER

KEEP OUT OF REACH OF CHILDREN. CORROSIVE. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, rubber gloves, and protective clothing. May be fatal if swallowed. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

(Required for product supplied in containers 50 lbs. or greater.)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

PESTICIDE STORAGE - Store in a dry place no lower in temperature than 50°F or higher than 120°F. Store in a tightly closed container in an area inaccessible to children.

(Water Soluble Packet) Store in a cool dry place. Do not handle packets with wet hands.

(Tablets) Store in a cool dry place. Do not handle tablets with wet hands.

(for products with industrial, institutional and commercial use sites)

CONTAINER DISPOSAL - Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container promptly after emptying.

(Containers 50 lbs. or 5 gallons or less)

Triple rinse as follows: Fill container ¼ full with water and recap. Agitate vigorously. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

(Containers greater than 50 lbs. or 5 gallons):

Triple rinse as follows: Fill container ¼ full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

PACKET DISPOSAL *(for tear open packets only)* - Do not reuse packet. Discard packet in trash.

PESTICIDE DISPOSAL - Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
AUG 6 2012

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1839-142

Tear Open Packet Label:

BTC[®] 2125M-P40 SANITIZER CONCENTRATED POWDER

ACTIVE INGREDIENTS

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chlorides	20.0%
Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl	
ethylbenzyl ammonium chlorides	20.0%
INERT INGREDIENTS	60.0%

Total	100.0%
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KEEP OUT OF REACH OF CHILDREN

DANGER

See master label for additional precautionary statements
and use directions.

Disposal - Do not reuse empty packet. Wrap packet and put in trash.

EPA REG. NO. 1839-142
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
22 West Frontage Road
Northfield, IL 60093

Mix contents of one packet into X gallons of water.

NET CONTENTS:

0.0625 ounce per packet per tablet or
0.125 ounce per packet per tablet or
0.1875 ounce per packet per tablet or
0.3125 ounce per packet per tablet or
0.625 ounce per packet per tablet or
1.25 ounce per packet per tablet

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Water Soluble Packet Label:

**BTC[®] 2125M-P40 SANITIZER
CONCENTRATED POWDER**

ACTIVE INGREDIENTS

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chlorides	20.0%
Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl	
ethylbenzyl ammonium chlorides	20.0%
INERT INGREDIENTS	60.0%

Total 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See master label for additional precautionary statements and use directions.

EPA REG. NO. 1839-142
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
22 West Frontage Road
Northfield, IL 60093

Add one packet to X gallons of water.

NET CONTENTS:

0.0625 ounce per packet per tablet or
0.125 ounce per packet per tablet or
0.1875 ounce per packet per tablet or
0.3125 ounce per packet per tablet or
0.625 ounce per packet per tablet or
1.25 ounce per packet per tablet

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8/8

**Alternate Water Soluble & Tear Open Packet Label:
(for small 1" x 1" packets)**

**BTC[®] 2125M-P40 SANITIZER
CONCENTRATED POWDER**

Quaternary Ammonium Chlorides

KEEP OUT OF REACH OF CHILDREN

DANGER CORROSIVE

See outer container for
Precautions and Directions

EPA REG. NO. 1839-142

NET CONTENTS: 0.0625 ounce or
0.125 ounce or
0.1875 ounce or
0.3125 ounce or
0.625 ounce or
1.25 ounce

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